

Perspectives on the Value of GHS

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Perspectives on Value of GHS

Topics

CSPA Approach
Benefits of GHS
OPP White Paper
Scope of Coverage
Industry Response

Perspectives on Value of GHS

CSPA represents manufacturers and formulators of non-agricultural pesticides:

Disinfectants, sanitizers, germicides

Insecticides, repellants, rodenticides

Any pesticide labeled for use in areas "in or around household premises"

Or for use on pets

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CSPA Approach

Implementation of GHS was not a matter of "IF" and "WHAT" but "WHEN" and "HOW"

Task was how best to implement change in a cost effective, practical and reasonable manner

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CSPA Approach

Ardent supporter of the objectives of GHS
Contributed to its development as member of Coordinating Committee on International Harmonization (CCIH)

Recognizes the many anticipated benefits of harmonization that will result from implementation of GHS

However, many of members have concerns about its implementation that must be addressed before proceeding

EPA Implementation of GHS

The Globally Harmonized System of Classification and Labeling of Chemicals: Implementation Planning Issues for the Office of Pesticide Programs

August 25, 2004 - EPA Office of Pesticide Program publishes White Paper
Comment period extended to Dec. 6, 2004
EPA Docket OPP-2004-2005

EPA Implementation of GHS

Scope of Coverage

Applies to all types of pesticides
Limit changes to those necessary to achieve consistency with GHS
Adopt only those GHS hazard classification criteria and label elements for all hazard classes for which OPP currently requires hazard labeling of pesticide products

EPA Implementation of GHS

Scope of Coverage

All GHS-prescribed label elements (pictograms, signal words and hazard statements) should appear together on the label
Pictograms would include a red border
Only one signal word would appear on each label

EPA White Paper: Industry Response

Principles:

Application of Building Block Approach

Limit adoption of GHS to Building Blocks that correspond to existing scope of regulations
EPA should continue to exempt indoor residential use products from requirements for labeling environmental endpoints

Consideration of Risk

Base hazard labeling of consumer products on consideration of risk ("likelihood of harm") for chronic effects

EPA White Paper: Industry Response

Principles:

Existing Data and Additional Testing

One Objective of GHS is to reduce the need for testing and evaluation of chemicals and mixtures
GHS is based on currently available data
Maximize use of existing information for C&L without mandating test methods
EPA should not require submission of additional test data due to shift in classification criteria for some endpoints
EPA should not impose any new test requirements on a product (for purposes of GHS compliance) that were not previously required

EPA White Paper: Industry Response

Principles:

Precedence of Human Data

Human experience should take precedence over other data
Consistent with NAS position regarding use of ethically obtained data from humans

Weight-of-Evidence Approach

Use a weight-of-evidence approach in classification decisions based on best available data

EPA White Paper: Industry Response

Principles:

Data Point Protection for Cite-All and Me-Too Registrations

Protection of Confidential Business Information

GHS calls for disclosure on label of ingredients that contribute to hazard classification

GHS provides that national rules governing disclosure of CBI will take precedence over ingredient disclosure provisions

OPP policies are consistent with GHS

EPA White Paper: Industry Response

Principles:

Focus on requiring information that meets needs of antimicrobial consumer product users

enhance comprehensibility

new GHS requirements must replace, not add to current precautionary statements – reduce clutter

align labeling requirements of indoor residential-use antimicrobial cleaning products with CPSC requirements for other consumer products –

consistent information

EPA White Paper: Industry Response

Specific Consideration by Hazard Class:

Current EPA Category IV Eye Irritants

- Covers pesticides that result in “minimal effects clearing in less than 24 hours”
- GHS would not classify products with such effects
- OPP plans to propose that these products be considered *unclassified*

EPA White Paper: Industry Response

Specific Consideration by Hazard Class:

Flammability and Other Physical Hazards

- OPP plans to adopt all GHS hazard classes and categories and corresponding label elements, including use of pictograms and signal words
- OPP would need to adopt each associated test method in OPPTS Series 830 Product Properties Test Guidelines – i.e., aerosol flammability

EPA White Paper

Implementation of GHS

OPP Implementation Options

Pilot Project

Timing and Transition

NAFTA Synchronization/Coordination

Outreach and Education

EPA White Paper

OPP Implementation Options

Option 1: Establish a separate review and approval process; *or*

Option 2: Integrate GHS label changes into on-going registration and re-registration actions

EPA White Paper: Industry Response

OPP Implementation Options

Support for Option 1

- Implement in phases by chemical or product category
- Competing products in same category labeled according to same set of requirements and timeline
- Avoid competitive advantage/disadvantage
- Maintain competitive level playing field
- Consider GHS labeling via notification

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Pilot Project

- Proposal to allow for voluntary submission of label amendments with GHS changes by registrants before final rules are in place
- Conduct *voluntary* pilot project before proposing amendments to regulation
 - Assist with determining feasibility of GHS label changes, realistic timelines and regulatory impact
 - Mock label exercise
- Economic Impact Analysis – “major rule?”

EPA White Paper: Industry Response

Timing and Transition

- OPP states that ideally rulemaking could be initiated in 2004 and completed in 2005 (It is now late 2006)
- Global implementation goal is 2008
- Suitable transition period (24-36 months)
- Stagger deadlines by phasing in requirements by product type, chemical, or chemical class
- Treatment of existing stock

EPA White Paper: Industry Response

NAFTA Coordination/Synchronization

- Consult with NAFTA Partners
- NAFTA TWG on Pesticides 5-Year Workplan
 - GHS Strategy for Implementation
 - “Under TWG, NAFTA countries are committed to implementing the GHS as it relates to pesticides in a coordinated manner”*
- Designation of USG Lead Agency

EPA White Paper: Industry Response

NAFTA Coordination/Synchronization

Canada

- Pest Control Products Sector Working Group
- PMRA Summary Discussion Document (April 2005)

NAFTA Coordination

- Comparison Document (December 2005)
- Identify differences in proposed approaches

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Outreach and Education

- Education and training is key
- Awareness-raising activities with OPP stakeholders (e.g., PPDC, SFIRIG)
- Creation of industry stakeholder group
- Conduct public stakeholder meetings and workshops
- Explore work sharing opportunities with States

EPA White Paper: Industry Response

Concerns

Exempt pesticides from GHS

Pesticides are registered and marketed domestically,
not internationally

Pesticides exempt from HazCom

FIFRA is a risk based regulation

Move from current 3-Signal Word System (Danger, Warning, Caution) to 2-Signal Word (Danger, Warning) under GHS

Products will be "re-classified" as more toxic

EPA White Paper: Industry Response

Concerns

Resulting impact to product classification will lead
to changes in:

Pesticide training programs reference materials

Worker protection standards

Applicator training

Personal protective equipment (PPE)
recommendations

State regulations

Statutory requirements

Commercial preference for products with "Caution

Loss of market

EPA White Paper: Industry Response

Concerns

Product Re-testing

Label Costs for revising (colors, pictograms)

Amount of information on labels needs to be
reduced (40 CFR 156 and Label Review Manual)

Environmental hazard symbol on end-use
products

Maintain level playing field

Lack of public stakeholder participation



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